



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
2443 WARRENVILLE RD. SUITE 210  
LISLE, IL 60532-4352

September 5, 2017

EA-17-048

Naveen Lal, M.D.  
Radiation Safety Officer  
Allen County Cardiology  
604 West Berry  
Fort Wayne, IN 46802

SUBJECT: ALLEN COUNTY CARDIOLOGY – NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$7,000; NRC ROUTINE INSPECTION REPORT 03035340/2016001(DNMS) AND INVESTIGATION REPORT 3-2017-002

Dear Dr. Lal:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) routine inspection conducted at your Fort Wayne, Indiana facility on October 18 and 21, 2016, with continued in-office review through November 10, 2016. The details of the inspection were documented in NRC Inspection Report No. 03035340/2016001(DNMS) issued on December 8, 2016, available on NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> as ML16343A183. On November 8, 2016, the NRC Office of Investigations (OI) initiated an investigation to determine if your nuclear medicine technologist willfully failed to perform required surveys and provided inaccurate and incomplete records of surveys to the NRC. The investigation was completed on March 9, 2017. The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with you during the telephonic exit meeting on May 22, 2017.

Based on the results of that inspection and investigation the NRC identified two apparent violations of NRC requirements: (1) the deliberate failure to perform daily ambient exposure rate surveys and provide information to the NRC that is complete and accurate in all material respects, as required by License Condition 15.A. and Title 10 of the *Code of Federal Regulations* (CFR) Section 30.9(a); and (2) the deliberate failure to perform weekly wipe tests and provide information to the NRC that is complete and accurate in all material respects, as required by License Condition 15.A. and 10 CFR 30.9(a).

In our letter dated June 23, 2017, (ML17177A458) we provided you with the opportunity to address the apparent violations by attending a predecisional enforcement conference, requesting Alternative Dispute Resolution (ADR), or providing a written response before we made our final enforcement decision. In a letter dated July 12, 2017, (ML17205A412) you provided a response to the apparent violations.

Based on the information developed during the inspection and investigation, and the information that you provided in your response dated July 12, 2017, the NRC determined that two deliberate violations of NRC requirements occurred. These violations are cited in the enclosed Notice and the circumstances surrounding them are described in detail in our letters dated December 8, 2016 and June 23, 2017.

The overarching root cause of the violations was your failure, as Radiation Safety Officer (RSO), to provide adequate oversight of the radiation safety program with respect to the required NRC surveys and records.

The NRC cannot tolerate deliberate violations of its requirements, and the technologist deliberately failed to perform the surveys and wipe tests, as well as deliberately failed to provide complete and accurate records to the NRC inspector. Although the actual safety significance associated with the missed surveys and wipe tests was limited due to the short half-lives of the radionuclides in use, the technologist's deliberate actions adversely impacted the NRC's ability to perform its regulatory oversight function. Therefore, the violations have been collectively categorized, in accordance with the NRC Enforcement Policy (Policy), as a Severity Level III problem. In accordance with the Policy, a base civil penalty in the amount of \$7,000 is normally considered for a Severity Level (SL) III problem.

Because the violations were deliberate, the NRC considered whether credit was warranted for both *Identification* and *Corrective Action* in accordance with the civil penalty assessment process described in Section 2.3.4 of the Policy. Credit was not warranted for *Identification* of violations because the NRC identified the violations. The NRC determined credit was warranted for *Corrective Actions* taken in response to violations, which results in a base civil penalty amount for the associated violation severity level and license type. Your corrective actions included completing discussions regarding the violations with the technologist, ensuring adequate time for the technologist to complete the required tasks, observing and interviewing the technologist on a regular basis, improving communication with the technologist, and conducting frequent audits. Additionally, you committed to performing audits on at least a semi-annual frequency by an outside health physics consulting service.

Therefore, to emphasize management oversight of the radiation safety program, and strict compliance with license conditions and NRC requirements, I have been authorized, after consultation with the Director, Office of Enforcement to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$7,000 for the SL III problem. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

If you disagree with this enforcement sanction, you may deny the violations, as described in the Notice, or you may request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's ADR program can be found at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>.

The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. If you are interested in pursuing this issue through the ADR program, please contact: (1) the ICR at (877) 733-9415; and (2) Mr. Richard Skokowski, Enforcement Officer at 630-810-4373 within 10 days of the date of this letter. You may also contact both ICR and Mr. Skokowski for additional information. Your submitted signed

agreement to mediate using the NRC ADR program will stay the 30-day time period for payment of the civil penalty and the required written response, as identified in the enclosed Notice, until the ADR process is completed.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance was achieved is already adequately addressed on the docket in your letter dated July 12, 2017. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and in ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

Sincerely,

***/RA by James Trapp acting for/***

Cynthia D. Pederson  
Regional Administrator

Docket No. 030-35340  
License No. 13-32243-01

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254 Payment Methods (Licensee Only)

cc: State of Indiana

Letter to Dr. Naveen Lai from Cynthia D. Pederson dated September 5, 2017

**SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$7,000; NRC ROUTINE INSPECTION REPORT 03035340/2016001(DNMS) AND INVESTIGATION REPORT 3-2017-002 – ALLEN COUNTY CARDIOLOGY**

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<b>OFC</b>	RIII-EICS	RIII	RIII	RIII	OGC
<b>NAME</b>	LSmith:jc by email	PRPelke	McCraw	Giessner	Mikula <sup>1</sup>
<b>DATE</b>	08/14/17	08/14/17	08/14/17	08/14/17	08/31/17
<b>OFC</b>	D:OE	RIII	RIII-ORA		
<b>NAME</b>	JPeralta2	Skokowski	CPederson		
<b>DATE</b>	08/31/17	09/01/17	09/05/17		

1 OGC concurrence provided via e-mail from Olivia Mikula on August 31, 2017  
 2 OE concurrence provided via e-mail from Juan Peralta on August 31, 2017

NOTICE OF VIOLATION  
AND  
PROPOSED IMPOSITION OF CIVIL PENALTY

Allen County Cardiology  
Fort Wayne, Indiana

License No. 13-32243-01  
Docket No. 030-35340  
EA-17-048

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on October 18 and 21, 2016, with continued in-office review through November 10, 2016, and an NRC Office of Investigations investigation completed on March 9, 2017, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and Title 10 of the *Code of Federal Regulations* (CFR) 2.205. The particular violations and associated civil penalty are set forth below:

- A. License Condition 15.A. requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in the application, dated May 27, 2010.

Item 10, "Radiation Protection Program," of the application states that the licensee has developed and will implement written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.

Title 10 of the *Code of Federal Regulations* (CFR) 20.1501(a) requires licensees to survey areas that:

- (1) May be necessary for the licensee to comply with the regulations in this part; and
- (2) Are reasonable under the circumstances to evaluate--
  - (i) The magnitude and extent of radiation levels; and
  - (ii) Concentrations or quantities of residual radioactivity; and
  - (iii) The potential radiological hazards of the radiation levels and residual radioactivity detected.

Bullet 1 of the licensee's "Standard Policy and Procedure- Area Surveys and Wipe Tests," requires, in part, "in radiopharmaceutical preparation and administration areas, surveys are to be done at the end of each day of use with a low range GM survey meter."

Title 10 CFR 20.2103(a) requires that each licensee shall maintain records showing the results of surveys required by 10 CFR 20.1501.

Title 10 CFR 30.9(a) requires that information provided to the Commission by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the licensee shall be complete and accurate in all material respects.

Contrary to the above, on several occasions between August 8 and October 18, 2016, Allen County Cardiology failed to conduct surveys in radiopharmaceutical preparation and administration areas at the end of each day of use with a low range GM survey meter. In addition, the records of those surveys, which were required to be maintained

by the licensee and were provided to the Commission during the inspections on October 18 and 21, 2016, were not complete and accurate in all material respects, in that the nuclear medicine technologist created inaccurate records to falsely indicate that these surveys had been performed.

- B. License Condition 15.A. requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in the application dated May 27, 2010.

Item 10, "Radiation Protection Program," of the application states that the licensee has developed and will implement written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70.

Title 10 CFR 20.1501(a) requires licensees to survey areas that:

- (1) May be necessary for the licensee to comply with the regulations in this part; and
- (2) Are reasonable under the circumstances to evaluate--
  - (i) The magnitude and extent of radiation levels; and
  - (ii) Concentrations or quantities of residual radioactivity; and
  - (iii) The potential radiological hazards of the radiation levels and residual radioactivity detected.

Bullet 1 of the licensee's "Standard Policy and Procedure- Area Surveys and Wipe Tests," requires, in part, "in any radiopharmaceutical preparation and administration areas, a weekly wipe test will be performed."

Title 10 CFR 20.2103(a) requires that each licensee shall maintain records showing the results of surveys required by 10 CFR 20.1501.

Title 10 CFR 30.9(a) requires that information provided to the Commission by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the licensee shall be complete and accurate in all material respects.

Contrary to the above, on several occasions between August 8, and October 13, 2016, Allen County Cardiology failed to perform a weekly wipe test in radiopharmaceutical preparation and administration areas for removable contamination. In addition, the records of those weekly wipe tests, which were required to be maintained by the licensee and were provided to the Commission during the inspections on October 18 and 21, 2016, were not complete and accurate in all material respects, in that the nuclear medicine technologist created inaccurate records to falsely indicate that these weekly wipe tests had been performed.

This is a Severity Level III problem (Section 6.3).  
Civil Penalty - \$7,000 (EA-17-048)

The NRC concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in your letter dated July 12, 2017. However, if the description therein does not accurately reflect your position or your corrective actions, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 within 30 days of the date of the letter transmitting this Notice of Violation. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation; EA-17-048", and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville, MD 20852-2738, with a

copy to the Regional Administrator, U.S., Nuclear Regulatory Commission, Region III, 2443 Warrenville Road, Suite 210, Lisle IL 60532, and the Document Control Desk, Washington, DC 20555-0001.

The Licensee may pay the civil penalty proposed above in accordance with NUREG/BR-0254 and submit to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice. Should the Licensee fail to answer within 30 days of the date of this Notice, the NRC will issue an order imposing the civil penalty. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation; EA-17-048" and may: (1) deny the violations listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the response should address the factors addressed in Section 2.3.4 of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205 should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty, which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above, i.e., Reply to Notice of Violation, Statement as to payment of civil penalty, and Answer to a Notice of Violation, should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 2443 Warrenville Road, Suite 210, Lisle IL 60532 and the Document Control Center, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 5<sup>th</sup> day of September 2017